FEB 21 2001

K003789

510(k) Summary

Submitter Information:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Debbie McIntire
Manager, Clinical and Regulatory Affairs

Telephone: (408) 341-0700
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Date Prepared: December 5, 2000

Device Name:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names:	Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear
	Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear
Classification Name:	Soft (Hydrophilic) Contact Lens
Device Classification:	Class II (21 CFR 886.5925)

Predicate Devices:

The IGEL 56 UV (hefilcon C) Soft (hydrophilic) Contact Lens was selected as the predicate device.

The Specialty 56 UV devices and IGEL 56 UV devices are manufactured in the same facility, under the same quality system, using the same formulation, molding, tinting, packaging and sterilization processes. The Specialty 56 UV lenses contain the same UV blocking agent as the IGEL 56 UV lenses, and the manufacturing process for adding the UV blocking agent is the same.

Description of Devices:

The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens is a single vision lens. The Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens is a lens for the correction of astigmatism associated with either near-sightedness (myopia) or far-sightedness (hyperopia) or a combination of both. The lens is able to correct astigmatism up to 7.00 diopters. The Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses are flexible, hemispherical, transparent shells of the following dimensions:

Single Vision Lens:

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at –3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Powers: -20.00 to +20.00

Toric Lens

- Chord Diameter: 14.0mm – 15.0mm
- Center Thickness: 0.09mm (at-3.00 D)
- Optic zone: variable with power
- Base Curve: 8.00mm – 9.00mm
- Sphere: -20.00 to +20.00
- Cylinder: Up to 7.00 D
- Axis: 1 to 180°
- Stabilizing Mechanism Dynamic Stabilizing Sectors

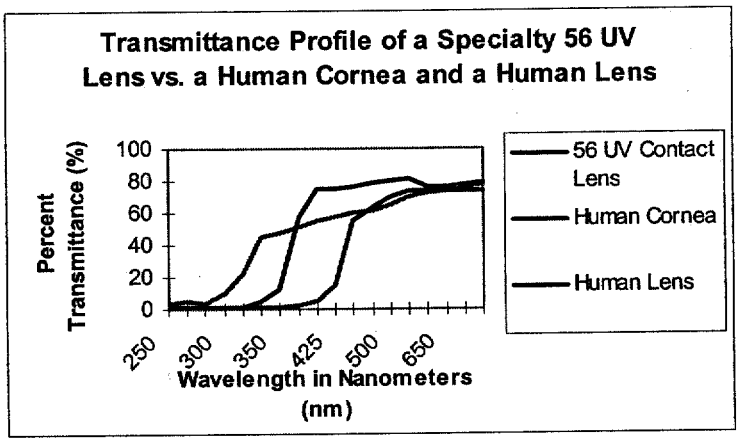
The lens material (hefilcon C) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-Vinyl pyrrolidinone and contains the UV absorbing compound 2-hydroxy-4-acrylethoxy benzophenone. The lens is swollen to equilibrium state in a sterile saline solution, and contains 44% hefilcon C with 56% water by weight when fully hydrated. The blue tinted lens contains D&C Green 6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses.

The physical properties of the lens are:

- Specific gravity: 1.16
- Refractive Index: 1.41, fully hydrated
- Light Transmittance : 94.5% clear (untinted)
  90.3% (blue handling tint)
- UV Transmittance: < 10%
- Surface Character: hydrophilic
- Water Content: 56% by weight in normal saline
- Oxygen Permeability (Dk)* : 21×10^{-11} (cm^2 /sec) (ml O_2 /ml x mm Hg) at 35°C

*[Fatt Method for determination of oxygen permeability]

The following graph compares the UV transmittance curve of the **Specialty 56 UV** (hefilcon C) Soft (Hydrophilic) Contact Lens (-7.00 D) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



Comparison to Predicate Device

PARAMETER ***Submission number***	***Specialty 56 UV, and Specialty 56 UV Toric Hydrophilic Contact Lenses for Daily Wear***	***IGEL 56 UV Soft (hydrophilic) Contact Lens for Daily Wear*** ***K984523***
Material	hefilcon C	hefilcon C
Material classification	Hydrophilic Lens Group 2	Hydrophilic Lens Group 2
indication for use	myopia, hyperopia, and astigmatism	myopia, hyperopia, and astigmatism
water content	56%	56%
Visible light transmittance	90.3%	90.3%
UV transmittance	< 10%	< 10%
Dk (35° C)	21×10^{-11}	21×10^{-11}
Powers	+20.00 to –20.00 Diopters	+6.00 to –12.00 Diopters
Color	blue visibility D&C Green No. 6	blue visibility, D&C Green No. 6
refractive index	1.41	1.41
specific gravity	1.16	1.16
Method of manufacture	Molded	Molded

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the single vision lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfection systems only.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Specialty 56 UV and the Specialty 56 UV Toric (hefilcon C) Contact Lenses for Daily Wear. Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. Extraction and analysis of the lenses showed no detectable extractables. The Specialty 56 UV lenses passed the requirements of sterility and stability testing.

A 4-week clinical trial on 37 subjects wearing lenses on a daily wear basis showed that the product is substantially equivalent to other lenses available on the market. No adverse events, significant slit lamp findings, or significant decreases in visual acuity were reported in the study. There was a low incidence of symptoms, problems and complaints, and study discontinuations. Lens wear time was essentially unchanged over the study period, and the lenses remained clinically clean during the study.

Conclusion:

Information submitted in the 510(k) establishes that the Specialty 56 UV and the Specialty 56 UV Toric (hefilcon C) Contact Lenses are comparable to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Ms. Debbie McIntire
Manager, Clinical and Regulatory Affairs
Specialty Ultravision, Inc.
307 Orchard City Drive
Suite 100
Campbell, CA 95008

Re: K003789
Trade Name: Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear and Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear.
Regulatory Class: II
Product Code: 86 LPL
Dated: December 5, 2000
Received: December 8, 2000

Dear Ms. McIntire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS STATEMENT

Device Names:

Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 56 UV Toric (hefilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

The **Specialty 56 UV (hefilcon C) Soft (Hydrophilic) Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism; for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in aphakic or not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K003789